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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/773,351 | 01/31/2001 | Daniel H. Maes | 00.22US | 5974 |

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05/01/2002

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EXAMINER

WILLIS, MICHAEL A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/773,351

Applicant(s)

MAËS ET AL.

Examiner

Michael A. Willis

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-- The MAILING DATE of this communication appears n the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's Request for Continued Examination of 12 April 2002 is entered. Claims 1-20 are pending. Any previous rejections that are not restated in this Office Action are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim 19 is rejected under 35 USC 112, 1st paragraph, for lack of enablement due to the phrase "or preventing".

Applicant argues that, while damage to the skin cannot be predicted in its entirety, there are specific types of damage that the skin may experience that are predictable. For example, applicant cites from US Patent Re. 36,068 that a decreased sensitivity to pain is a predictable characteristic of sun-damaged skin. Further, applicant argues that damage that is "associated" with a reduction or loss of skin barrier function includes UV-damage, degradation of collagen, and wrinkling and skin atrophy. Applicant argues that there is an ability to predict with great accuracy the damage associated with a reduction or loss of skin barrier function.

In response, applicant's assertion that there is an ability to predict with great accuracy the damage associated with a reduction or loss of skin barrier function is completely without merit. To the examiner's knowledge, there is no data to allow such a prediction. For example, there is no data in the specification or the prior art that would allow one of ordinary skill in the art to predict the exact number of skin wrinkles on a

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particular individual's face given a measurement of 32% reduction of skin barrier function for that individual. While the examiner concedes that broad correlations may exist between the loss or reduction of skin barrier function and various trends in the pathology of skin, such correlations neither prove causality nor allow for accurate predictions in any particular individual. Simply put, the prediction of the exact amount of skin pathology such as the level of collagen degradation or skin atrophy in an individual based on the measurement of skin barrier function is beyond the current state of the art. Without such predictive capability, a claim to the prevention of such symptoms lacks enablement.

With respect to the definition of "prevention", applicant provides a dictionary definition as "to keep from occurring". Applicant argues that to reduce a condition that already exists inherently prevents that condition. This is incorrect. Treatment of a condition after the fact is quite different from prevention. For example, a vaccine to prevent an infection is different from antibiotic treatment after infection has occurred.

Claims 1-20 are rejected under 35 USC 103(a) as being unpatentable over Ribier et al (US Pat. 5,650,166) in view of Subbiah (US Pat. 6,150,381) for reasons as stated previously.

Applicant argues that the example of vesicle formation by simple stirring as pointed out previously by the Examiner "does not teach or suggest a simple mixture of an exfoliant and cholesterol sulfate which are the actives of the present invention".

In response to applicant's argument, the test for obviousness is not that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, the teachings of Ribier and Subbiah suggest a mixture of exfoliant and cholesterol sulfate. Applicant's argument that Ribier does not teach N-acetyl glucosamine as being a surface diffusing active is moot, because such a teaching is not required to suggest the mixture of N-acetyl glucosamine and cholesterol sulfate. As stated previously, the term "mixture" is not limited to random solutions, but includes ordered compositions such as vesicles.

Applicant argues that the '166 reference teaches away from the instant invention of a "simple mixture" because of the use of vesicles in the '166 reference. However, as stated previously, applicant's reliance on the features of a "simple mixture" is not supported by the claims or the specification. The specification clearly states that "the combination of these two components can be applied in any type of cosmetically or pharmaceutically acceptable vehicle for topical application with which the active component is compatible" (page 5, lines 12-13 of the specification). The term "mixture" as claimed is broadly interpreted by the examiner to include both random and ordered compositions.

Conclusion

This is an RCE. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action of the RCE. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

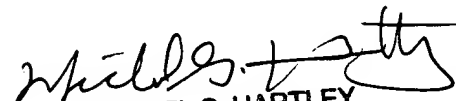
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis
Examiner
Art Unit 1617

April 25, 2002



MICHAEL G. HARTLEY
PRIMARY EXAMINER